IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT BECKLEY

RYAN HYSELL and CRYSTAL HYSELL,
on behalf of their daughter, A.H., a minor,

Plaintiffs,

v. Civil Action No. 5:18-cv-01375

RALEIGH GENERAL HOSPITAL,
and THE UNITED STATES OF AMERICA,

Defendants.

REPLY IN SUPPORT OF DEFENDANT UNITED STATES OF AMERICA'S MOTION TO VACATE, ALTER, AND/OR AMEND THE JUDGMENT ENTERED IN THIS CIVIL ACTION AND/OR FOR NEW TRIAL

I. INTRODUCTION

Plaintiffs' attempt to justify the Court's finding of proximate causation relies on the testimony of Dr. Alia Marie Iqbal O'Meara which cannot be linked to the acts or conduct of Certified Nurse Midwife Debra Crowder ("CNM Crowder"). Dr. O'Meara's causation testimony lacked a causal link to an alleged breach in the standard of care by CNM Crowder based on the testimony of Plaintiff's midwife expert, John Fassett, CNM ("CNM Fassett"). Plaintiffs never elicited sufficient expert testimony from any of the experts who testified at trial to support a reasonable inference to establish such a causal link as required by the law. Simply put, Plaintiffs failed to elicit testimony from any of the experts at trial that something CNM Crowder did or did not do caused their alleged injuries. This case involved complex medical issues which required expert testimony not only on the standard of care but also on the issue of proximate cause. Further, the Court's independent recalculation of the Apgar scores was not supported by any expert testimony.

Plaintiffs contend in their response that the United States must establish clear error to "vacate, alter, or amend" the Court's verdict. (*See* ECF No. 352.)[1] The United States met its burden in the pending motion by demonstrating the absolute lack of evidence supporting the verdict, particularly with respect to proximate causation, and the overwhelming trial testimony supporting the opposite outcome. Its position is undoubtedly reinforced by the entirety of the expert testimony heard by the Court at trial. As the Supreme Court has stated multiple times, "[a] finding is 'clearly erroneous' when although there is evidence to support it, the reviewing court ***on the entire evidence*** is left with the definite and firm conviction that a mistake has been committed." *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948) (emphasis added). *See also Anderson v. City of Bessemer City*, 470 U.S. 564, 573 (1985) (same); *Butts v. United States*, 930 F.3d 234, 238 (4th Cir. 2019) (same), *cert. denied*, 140 S. Ct. 1113 (2020).

Finally, the pending motion does not "re-litigate this case" as Plaintiffs aver. (ECF No. 352 at 1.) Rather, it lays out specific portions of the trial transcript to show the Court that its decision was based on clearly erroneous findings. The response filed by Plaintiffs does not provide support for upholding the current verdict. Plaintiffs twist the applicable standards to urge the Court that its decision must be blindly confirmed based on the testimony of CNM Fassett and Dr. O'Meara. That argument is without merit because any judgment rendered in favor of Plaintiffs based on their testimony would be a clear mistake as it is not supported by substantial evidence in the record of this case. As the Fourth Circuit held in *Butts*, although "clear error review is deferential, it is not toothless." 930 F.3d at 238. Clear error occurs when the findings under review are not supported by substantial evidence in the record. *Id.* In this case, the Court's judgment cannot stand because it is

[1] While Plaintiffs spent a good deal of time in their memorandum in opposition discussing Fed. R. Civ. P. 52(b) and Fed. R. Civ. P. 59(e), it is important to note that these rules were "adopted 'to mak[e] clear that the district court possesses the power' to rectify its own mistakes in the period immediately following the entry of judgment." *White v. N.H. Dep't Empl. Sec.*, 455 U.S. 445, 4550 (1982).

not supported by substantial evidence in the record, and letting the judgment stand would be clear error, resulting in manifest injustice against the United States.

II. IT WAS CLEAR ERROR TO CONCLUDE THAT CNM CROWDER WAS NEGLIGENT IN HER CARE OF MRS. HYSELL AND A.H.

Plaintiffs claim in their response that the United States has abandoned the part of its motion directed toward the Court's finding on negligence. (*See* ECF No. 352 at 4 n.1.) That is not the case. Despite the United States' strategic decision to devote the vast majority of its memorandum of law focusing on the element of causation, the United States did not waive this argument, which is clearly included in the pending motion. (*See* ECF No. 343 at 1 ¶ 2.)[2] Analysis of the entire evidence admitted at trial shows that a clear error was made with regard to negligence.

Plaintiffs proffered CNM Fassett as an expert in the field of certified midwifery. Tr. at 267. CNM Fassett, who has testified for Plaintiffs' law firm three times prior to this case, (Tr. at 359), is the ***only*** expert called by Plaintiffs who could and did testify as to the standard of care applicable to the conduct of CNM Crowder in this case. As the Court concluded, CNM Fassett's sole opinion critical of CNM Crowder was that the fetal monitoring strip was uninterpretable for an approximately two-hour period during labor from 12:20 p.m. to 2:19 p.m. *See* Tr. at 335–36, 343.

However, CNM Fassett had no criticisms of Ms. Crowder from the time she came on duty the morning of October 29, 2010, through 12:20 p.m. that day. Tr. at 349. Further, he did not have any criticism of her once the fetal scalp electrode was placed at 2:19 p.m. Tr. at 354–56. He also admitted that during that approximately two-hour period (12:20 p.m. to 2:19 p.m.), he could not testify to a reasonable degree of medical probability that the baby was in fetal distress at any point or what happened during that two-hour period. Tr. at 356, 358. CNM Fassett also admitted that he had no

[2] Courts are permitted to review an issue not pressed so long as the issue has been passed upon by the trial court. *Lebron v. Nat'l R.R. Passenger Corp.*, 513 U.S. 374, 379 (1995); *United States v. Williams*, 504 U.S. 36, 41 (1992); *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1099 n.8 (1991). Since the standard of care issue was raised in the motion and this Court has passed on the issue of the standard of care, the issue has been preserved for review purposes.

opinions on causation. Tr. at 358. CNM Fassett's testimony on the standard of care is unsupported elsewhere in the record and is heavily outweighed by the other expert testimony heard by the Court at trial. *See U.S. Gypsum Co.*, 333 U.S. at 395 (noting that clear error has been made when a finding is not supported by the entire evidence); *Butts*, 930 F.3d at 238.

Dr. Mark Landon is a double board certified as an obstetrician/gynecologist and a maternal-fetal medicine specialist and currently serves as Professor and Chairman of the Department of Obstetrics and Gynecology. He has been a long-standing examiner for the American Board of Obstetrics & Gynecology in both general obstetrics and gynecology and maternal-fetal medicine, served as reviewer for at least seven peer-reviewed journals, is chief editor of *Gabbe's Obstetrics* (leading treatise in the field), and authored over 200 articles and numerous book chapters in obstetrics and gynecology and mater-fetal medicine. Tr. at 1889–95. Dr. Landon attends labor and delivery, delivers babies on a regular basis, is in charge of labors and deliveries weekly, and sees outpatients in the clinic up to two days per week. Tr. at 1891. Notably, Dr. Landon was a contributor and task force consultant for the 2014 Task Force Report titled *Neonatal Encephalopathy and Neurological Outcome*, published by the American College of Obstetricians and Gynecologists and the American Academy of Pediatrics which was widely discussed at trial. Tr. at 1895–96. He is the only expert in this trial who served on that task force and/or contributed to its report.

Additionally, Dr. Landon has supervised and taught midwives concerning the labor and delivery of babies and how to interpret fetal monitoring strips for at least the past fifteen years. He has also taught medical students, residents, and fellows how to interpret electronic fetal monitoring strips for forty years. Tr. at 1897–98. Thus, he is intimately familiar with the standards of care "applicable to interpreting electronic fetal monitoring strips that were in effect at the time of the events involved in this case" and was qualified as an expert at trial without objection "as an expert in obstetrics and gynecology, maternal-fetal medicine, the standards of care applicable to midwives, and

also the standards of care applicable to interpreting fetal monitoring strips at the time of the events involved in this case." Tr. at 1898–99. Dr. Landon was by far the most qualified expert who testified at trial on the subjects of electronic fetal monitoring, obstetrics, and maternal-fetal medicine.

Dr. Landon testified to a reasonable degree of medical probability that CNM Crowder met the standard of care when she was managing Mrs. Hysell's labor and delivery resulting in the birth of A.H. Tr. at 1915. He explained that "the conduct of the labor, the fetal monitoring, the actions associated with fetal monitoring, or alleged inactions, in [his] opinion all fall within the standard of acceptable medical care." *Id.* Thus, he "concluded that Ms. Crowder met the standard of care, and [he] concluded that nothing that Ms. Crowder did or did not do, for that matter, resulted in [A.H.'s] unfortunate brain injury." Tr. at 1924.

Dr. Ernest Graham from Johns Hopkins University is a maternal-fetal medicine specialist focusing on high-risk pregnancies. Tr. at 915. Dr. Graham, like Dr. Landon, is double-board certified in general obstetrics and gynecology and maternal-fetal medicine. Tr. at 918. He has won numerous awards for his case reviews, given lectures all around the world on many of the issues involved in this case, such as lectures on Intrapartum Fetal Monitoring, and has published sixty-nine peer-reviewed articles in publications like the Journal of Maternal-Fetal and Neonatal Medicine, and Obstetrics and Gynecology. Tr. at 920–25. Dr. Graham also testified that CNM Crowder met the standard of care. Tr. at 927. Notably, Dr. Graham was not retained by the United States in this case.

Thus, based on the entirety of the evidence, particularly in light of the testimony of Dr. Landon and Dr. Graham, and comparing their experience and credentials with those of CNM Fassett, it was clear error to find that CNM Crowder failed to meet the applicable standard of care.

III. IT WAS CLEAR ERROR TO DETERMINE THAT CNM CROWDER PROXIMATELY CAUSED AN INJURY TO PLAINTIFFS

"It is axiomatic that in a medical malpractice lawsuit such as the instant case, a plaintiff must establish that the defendant doctor deviated from some standard of care, and that the deviation

was 'a proximate cause' of the plaintiff's injury. W.Va.Code, 55–7B–3 [1986]." *Mays v. Chang*, 579 S.E.2d 561, 565 (W.Va. 2003) (footnote omitted). Thus, Plaintiffs have the burden to prove by a preponderance of the evidence that the sole allegation of negligence against CNM Crowder (the United States)—that she should have adjusted the fetal hear rate monitor to make the electronic fetal monitor strip more interpretable from 12:20 p.m. to 2:19 p.m.—was a proximate cause of A.H.'s injury. It is clear from the evidence presented at trial that Plaintiffs failed to meet that burden.

As the Court notes in its memorandum opinion, proximate causation must be proven through expert witness testimony. *See Fitzgerald*, 679 F.2d at 350. Although proximate causation may be proven in some cases through ***reasonable*** inferences, those inferences must be based upon the proper expert testimony which establishes a clear causal link between the alleged negligence and the alleged injury. *See Dellinger v. Pediatrix Medical Group, P.C.*, 750 S.E.2d 668, 677 (W. Va. 2013); *Sexton v. Greco*, 613 S.E.2d 81, 84 (W. Va. 2005). However, expert testimony offered on causation must nevertheless be stated "in terms of a reasonable probability." *Hovermale v. Berkeley Springs Moose Lodge*, 271 S.E.2d 225 (W. Va. 1980). Plaintiffs' never elicited testimony from their own experts or any expert of the defendants to a degree of reasonable probability that any alleged negligence by CNM Crowder caused an injury to A.H. All of the testimony cited by the Court in support of its finding on proximate causation only dealt with mere possibility (and not reasonable probability) and none of that testimony established a causal link between CNM Crowder and A.H.'s outcome. As such, the Court's analysis of proximate causation in this matter is based on clearly erroneous findings and is insufficient as a matter of law. *See Tyger Const. Co. Inc. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994); *Waffen v. U.S. Dep't of Health & Human Servs.*, 799 F.2d 911, 918 (4th Cir. 1986). (*See also* ECF No. 344 (citing numerous cases on these issues).)

A. Plaintiffs failed to establish a causal link between any alleged negligence of CNM Crowder and any alleged injury of A.H.

The Court found, based on the testimony of CNM Fassett, that the ***only*** potential breach of the standard of care proven by CNM Crowder was that the infant was not monitored properly for a period of approximately two hours (12:20 to 14:19) which occurred thirty-six minutes prior to delivery. However, CNM Fassett was unable to state what occurred during that period of time:

> Q. Okay. And during those times when it was uninterpretable, you can't render an opinion as to what was actually occurring during those periods of time, can you?
>
> A. I cannot.

(Tr. 356). Since he was unable to state any opinion as to what happened during that period of time, he obviously could not opine that had electronic fetal monitor been adjusted to make the strip interpretable during that period of time that (12:20 p.m. to 2:19 p.m.) it would have shown any hypoxia that would have been of sufficient duration to have injured A.H.

CNM Fassett's testimony on cross-examination established that his opinions could not support a finding that A.H. experienced hypoxia prior to delivery: (1) the fetal heart strip was Category I[3] prior to 12:20 p.m.; (2) he ***could not*** state there was fetal distress during the two-hour period at issue; (3) he never testified that hypoxia occurred from 2:19 p.m. when the fetal scalp electrode was placed through the time of delivery; (4) A.H. had normal Apgar scores after birth; and (5) the fetal heart strip was a Category II and never became a Category III after 12:20 p.m. *See* Tr. at 357, 361, 372. In fact, CNM Fassett testified that the electronic fetal monitor strip did reveal the baby's heart pattern at various times during the two-hour period at issue and that when detected, the pattern showed appropriate moderate variability and accelerations which were reassuring signs. He also agreed that

[3] Trial testimony established that Category I fetal heart patterns show that a fetus is healthy and well-oxygenated. On the other end of the spectrum, Category III patterns show that a fetus has suffered some insult to its acid-base balance of its blood, often due to hypoxia or anoxia. Category II strips are all those not considered Category I or III, and one cannot draw either conclusion from them. *See* Tr. at 369–70 (Fassett Test.).

there was never an absence of variability. CNM Fassett also testified that the requirements in the ACOG decision tree for Category II strips was followed. Tr. at 351-54, 371-73.

CNM Fassett acknowledged that he could not offer any opinions as to causation and that the midwife's responsibility for the infant ended when she gave the baby to RGH nurses at the time of delivery. He testified that he could not opine that anything occurred when the strip was allegedly uninterpretable had any effect on A.H.'s outcome. *See* Tr. at 348, 358, 360–61.

Since CNM Fassett could not render an opinion on causation, Plaintiffs had to elicit testimony from another expert witness that A.H. suffered an injury during that exclusive timeframe from 12:20 p.m. to 14:19 p.m.. None of the other experts called to testify by the Plaintiffs provided such testimony *See* discussion *infra* Part III.C.

As Plaintiffs agreed, Dr. O'Meara, a pediatric intensivist, did not offer any opinion as to the standard of care of the midwife in this case. While Plaintiffs' response focuses on the United States' failure to object at trial to Dr. O'Meara's qualifications as a pediatrician, she never rendered any opinions about the standard of care for midwives or CNM Crowder. *See* Tr. at 566, 662. She did not have any knowledge of midwifery, did not "have familiarity with fetal monitoring strips," and had not delivered a baby since medical school. Tr. at 562, 604. Dr. O'Meara's testimony focused on the resuscitation after delivery which was after CNM Crowder's duty of care ended. Tr. at 348.

Nothing in Dr. O'Meara's testimony supports an inference that CNM Crowder caused, much less proximately caused, a hypoxic event to occur to A.H. Dr. O'Meara never provided any testimony to a reasonable degree of medical probability that any alleged injury occurred within the timeframe of 12:20 p.m. to 2:19 p.m. (and Plaintiffs' counsel did not ask her for such an opinion). The Court's decision alludes to the cause of hypoxia being the umbilical cord of the infant impeding delivery, requiring CNM Crowder to reposition the cord so that delivery could proceed. (*See* ECF No. 335 at 3.) However, CNM Fassett did not opine that the position of the cord was caused by CNM Crowder

or that CNM Crowder improperly managed the cord once it was discovered. *See* Tr. at 312. CNM Fassett only testified that at most a cord compression ***can*** lead to less oxygen. *See id.* Moreover, the evidence at trial from the Plaintiffs indicated that the alleged cord issue occurred after 2:19 p.m. and was quickly recognized and managed and that delivery occurred almost immediately after the cord issue was resolved. Tr. at 1111-12; 1434. CNM Fassett never testified that CNM Crowder breached the standard of care regarding the management of any cord issue. Thus, there is no expert testimony supporting a breach in the standard of care by CNM Crowder regarding any umbilical cord issue or that such an issue played a role in causing a perinatal hypoxic-ischemic event during the period from 12:20 p.m. to 2:19 p.m. or at any other time. *See also* Tr. at 1912-13; 1915-16.

The ***most*** that can be said upon considering the testimony of CNM Fassett and O'Meara—and ignoring the testimony of every other relevant expert from trial supporting the contrary—is that the infant was not completely monitored for a period of two hours prior to birth, she was adequately monitored in the thirty-six minutes prior to birth, and the fetal monitor strip remained in Category II. When the fetal heart rate was monitored by the scalp electrode beginning at 2:19 p.m. and through the delivery at 2:55 p.m., the fetal monitoring strip showed moderate variability and accelerations, both of which are indications of good fetal oxygenation. As Dr. Landon testified, these findings indicated that that no hypoxia occurred during the two-hour period that Plaintiffs claim the strip was uninterpretable, because if hypoxia had occurred during that period of time, then the electronic fetal monitor strip would not have had these reassuring findings at the end prior to birth. He also testified that if a cord issue had existed, the fetal monitor strip showed no evidence of hypoxia from that event. Tr. 1904-11, 1916-19.

CNM Fassett and Dr. O'Meara never testified that a causal link existed between the alleged negligence of CNM Crowder and A.H.'s outcome. Thus, there was no reasonable expert testimony to support a reasonable inference to cure Plaintiffs' inability to elicit testimony of any injury during

the alleged two-hour period in which the fetal monitoring strips were allegedly uninterpretable. While CNM Fassett testified that the uninterpretable strip from 12:22 p.m. to 2:19 p.m. represented a breach in the standard of care, Dr. O'Meara never testified that this alleged breach affected the outcome. Her testimony focused on her claim that the baby needed resuscitation after delivery—which was after CNM Crowder's duty to the baby had ended. Concrete expert testimony linking the two was required, and such testimony was not elicited at trial, rendering the Court's conclusion simple *ipse dixit*. *See Fitzgerald*, 679 F.2d at 350; *Bellomy v. United States*, 888 F. Supp. 760, 764 (S.D. W. Va. 1995). The fact that it was not possible to tell what happened from 12:22 p.m. to 2:19 p.m., one way or the other, indicates that any inference that the child was potentially hypoxic during that period is pure speculation and unreliable. *See Huskey v. Ethicon, Inc.*, 29 F.Supp.3d 691, 729 (S.D.W.Va. 2014) (expert opinion testimony was excluded where she was unable to state one way or the other whether prior back surgery was causing plaintiff's pelvic pain but could not rule it out as a possible cause was held to be speculation and unreliable and helpful to the jury).

B. Testimony that an event could possibly cause an injury cannot serve as the basis for proximate causation.

The Court's opinion did not grapple with Plaintiffs' failure to produce any specific evidence that that hypoxia occurred during the two-hour period when CNM Fassett opined CNM Crowder's conduct fell below the standard of care and that such failure was a cause of A.H.'s alleged injuries. Moreover, Dr. O'Meara's testimony regarding hypoxia was not linked to Plaintiffs' allegations of negligence by CNM Crowder..

Plaintiffs refer to the testimony of Dr. Thomas Rugino as supporting their position on causation, but Plaintiffs stipulated that Dr. Rugino was not providing any opinions as to when A.H. may have been injured. *See* ECF No. 267. Dr. Jerome Barakos also never testified that CNM Crowder proximately caused an injury to A.H. He only testified that the MRI scans indicated that A.H. had a hypoxic injury at some point during the period between twenty-four weeks of gestation and one to

two years after birth. Dr. Barakos was unable to narrow that range any further. Tr. at 1208–09. Again, neither expert's testimony is causally linked to any alleged negligence by CNM Crowder.

In Plaintiffs' attempt to discredit the opinions of Defendants' experts, counsel asked series of questions regarding whether hypoxia can possibly cause a host of symptoms—all symptoms that A.H. had or has. While the experts acknowledged that hypoxia ***could possibly*** cause those symptoms, they opined that a host of other causes could also lead to the same outcome. *See, e.g.*, Tr. at 761–63 (Gropman Test.); Tr. at 1315 (Shimony Test.); Tr. at 1806–10 (Scher Test.); Tr. at 1858–59, 1886 (Bedrick Test.); Tr. at 1940–45 (Landon Test.). Thus, Plaintiffs never elicited testimony that, to a reasonable degree of medical probability (more likely than not) that a hypoxic-ischemic event occurred between 12:22 p.m. and 2:19 p.m. and caused A.H.'s injuries. Relying only on the remote possibility that something could have happened at an undefined point in time is insufficient to establish medical malpractice under the Medical Professional Liability Act. *See* W. Va. Code § 55-7B-3. *See* ECF No. 344 at 7–8 (citing cases).

C. A review of the entire evidence demonstrates that a clear error was made with respect to proximate causation.

The United States emphasizes that the Court's reasonable inference finding on proximate causation relies on the testimony of a lone expert, Dr. O'Meara. She was never qualified as a standard of care midwifery expert and expressed no opinions regarding CNM Crowder. Tr. at 566, 662. Further, her testimony was never connected to the standard of care opinion of CNM Fassett. She never testified that CNM Crowder's alleged breach regarding the adequacy of the monitoring from 12:19 p.m. to 2:19 p.m. played any role in the outcome of the case. A review of the other experts' qualifications and testimony on causation highlights the clear error made by the Court in relying on an unsupported and improper inference based on the testimony of Dr. O'Meara that A.H. experienced a hypoxic injury while at RGH.

Dr. Alan Bedrick is Professor of Pediatrics within the University of Arizona College of Medicine's Department of Pediatrics and has held other teaching, clinical, and leadership positions in pediatrics and neonatology at various institutions throughout his almost forty-year career and was qualified as an expert in his fields without objection. He has treated babies who have experienced hypoxic-ischemic injuries to their brains either during labor and delivery or after they have been delivered and has been called into labor and delivery rooms to attend to babies who might be suspected of having experienced hypoxia during labor and delivery. Tr. at 1828-33. Dr. Bedrick testified to a reasonable degree of medical probability that A.H. did not experience a hypoxic-ischemic brain injury during the period of labor or delivery and "did not experience any process which would cause neonatal brain injury during that hospital stay." Tr. at 1840. He further opined that A.H. "showed no signs of . . . neonatal encephalopathy" and "no signs of an acute neurologic syndrome. Her course was typical for a normal newborn infant." Tr. at 1844–45. Finally, relying on the testimony of Drs. Barakos, Sze, and Shimony that zero gray matter appeared damaged in A.H.'s MRI brain scans, Dr. Bedrick further testified that A.H.'s brain scans do show an acute hypoxic event. Tr. at 1882–83.

Dr. Mark Scher, a trained pediatric neurologist "with a particular interest in maternal and pediatric health dealing with fetal and neonatal neurology," was qualified without objection as an expert in pediatric neurology. Tr. at 1777, 1786. Dr. Scher was Chief of Pediatric Neurology at University Hospital Cleveland Medical Center's Department of Pediatrics from 1997 to 2017 before moving on to focus on clinical care and teaching, and he currently serves as emeritus tenured professor of pediatrics and neurology at Case Western School of Medicine. Tr. at 1780–81. He was triple board-certified and had numerous publications in his fields of medicine. Tr. at 1783–85. Dr. Scher testified to a reasonable degree of medical probability that "[A.H.'s] problem was a developmental problem beginning during the first half of pregnancy." Tr. at 1792–93. *See also* Tr. at 1802. He

further opined to a reasonable degree of medical probability that there was "a combination of gene and environment interactions" that caused A.H.'s neurological problems, none of which involved a hypoxic-ischemic event during the time of labor or delivery. *See* Tr. at 1793–94; *see also* Tr. at 1797 ("My opinion is there's no contributory asphyxia hypoxic-ischemic injury to the brain during that period of time."), 1802 ("[A.H.] did not have a neurological brain disorder we call neonatal encephalopathy associated with hypoxia-ischemia as a newborn."). Dr. Scher concluded that none of the events occurring at or around the time of delivery, up through the time A.H. was discharged from RGH on October 31, 2010, caused an injury to A.H. or her brain. Tr. at 1795.

Dr. Peter Giannone, Chief of Neonatology and regularly practicing neonatologist at Kentucky Children's Hospital and Professor of Pediatrics at the University of Kentucky College of Medicine, was qualified by the Court as an expert in the field of determining whether or not A.H. sustained any injury that caused her brain damage during labor and delivery. Tr. at 1517-20, 1528–30. After stating the bases for his various opinions, Dr. Giannone testified that there was no "reasonable scientific basis to conclude that [A.H.] experienced brain-damaging hypoxia from the time of delivery through the time in the newborn nursery." Tr. at 1557. He explained to the jury that not "a single one of th[e] entries" within A.H.'s newborn nursey record was "consistent with neonatal encephalopathy." Tr. at 1559. Finally, Dr. Giannone testified to a reasonable degree of medical probability that A.H. did not have an injury "as a result of untreated hypoxia during labor and delivery or up to the time she was discharged." Tr. at 1565.

Dr. Andrea Gropman, Professor of Pediatrics and Neurology and Chief of Neurogenetics and Neurodevelopmental Pediatrics at George Washington University and Children's National Medical Center as well as Director of Neurodevelopmental Disability at Children's National Medical Center, is board certified in five areas: pediatrics, neurology with special competence in child neurology, medical genetics, neurodevelopmental disorders, and biochemical genetics. Tr. at 712–18. She was

widely published in journals and medical treatises in her areas of specialties. Tr. at 722. Dr. Gropman was found by the Court "as qualified in pediatric neurology and pediatric neurogenetics, biogenetics, imaging of children's brain[s], causation or lack thereof of the claims, and the resources reasonably necessary in the future for her." Tr. at 724. Dr. Gropman opined to a reasonable degree of medical probability that A.H. did not experience brain-damaging hypoxia during her labor and delivery; neither MRI scan showed a pattern associated with hypoxia during that time; and no MRI or report reasonably supports the claim that A.H. suffered perinatal hypoxia causing permanent injury to her brain. Tr. at 727–28. *See also* Tr. at 773–76.

Dr. Gary Trock, a practicing neurologist who is board certified in pediatrics, neurophysiology, neurology with special competence in child neurology, and sleep medicine, was found qualified by the Court as an expert in pediatric neurology with the expertise to address the claim that A.H.'s injuries are due to perinatal asphyxia or hypoxia. Tr. at 960–62, 967. Dr. Trock testified to a reasonable degree of medical certainty that A.H. suffered a brain injury known as periventricular leukomalacia ("PVL") between twenty-eight weeks and thirty-six weeks gestation. Tr. at 970–73 (noting that beyond thirty-six weeks, the brain injury appearing in A.H.'s MRIs "can't occur"). Dr. Trock also opined to a reasonable degree of medical certainty that A.H. did not have neonatal encephalopathy and that her autism spectrum disorder "is not something caused by a hypoxic-ischemic insult." Tr. at 975, 979, 987–88.

Dr. Mark Landon, detailed for the Court the applicable categories of fetal monitoring strips and the elements that midwives should be observant of when examining the strips. Tr. at 1901–03. From the time when the fetal monitor was placed on Mrs. Hysell through the placement of the fetal scalp electrode at approximately 2:20 p.m., Dr. Landon testified that there was no evidence "whatsoever" that A.H. was "suffering from hypoxia during the labor and delivery." Tr. at 1904-11. Further, there was normal variability at 2:20 p.m. once the scalp electrode was placed, and normal

variability continued through delivery at 2:55 p.m. with no evidence of hypoxia Tr. at 1911–12 ("[T]his represents . . . a metabolically normal fetus without hypoxia, let alone acidosis capable of causing injury to the brain."). Dr. Landon also opined that no evidence could be deduced from the strip during the two-hour period which CNM Fassett stated that the strip was uninterpretable that A.H. experienced hypoxia and that to conclude otherwise would not be a reasonable conclusion. Tr. at 1916–18.

Dr. Joshua Shimony, a practicing board-certified neuroradiologist at several hospitals in the St. Louis area and Director of Pediatric Neuroradiology at Washington University Medical Center was qualified by the Court "as an expert on the review of MRI studies, the interpretation of those studies, and the cause and timing of injuries to children as reflected on those types of imaging studies." Tr. at 1232-37, 1247–49, 1254. Dr. Shimony testified to a reasonable degree of medical certainty that the pattern of injury seen on A.H.'s MRI scans "occurs typically towards the end of the second trimester and beginning of the third trimester." Tr. at 1257. *See also* Tr. at 1269, 1285, 1316–18. Dr. Shimony further opined that the pattern of injury on the MRI scans was not consistent with a "hypoxic-ischemic injury during the delivery process" and further testified that A.H.'s MRI scans did not show any damage to the gray matter of her brain, which is associated with hypoxic-ischemic encephalopathy at the time of birth. Tr. at 1258–62, 1283. He concluded, to a reasonable degree of medical probability, that A.H.'s brain injury occurred in utero and prior to her admission to RGH and not while A.H. was at RGH. *See also* Tr. at 1288.

Finally, Dr. Gordon Sze, thirty-year Chief of Neuroradiology at Yale University Medical Center and past President of the American Society of Neuroradiology, the largest scientific society of radiology in the world, was qualified as an expert in neuroradiology. Tr. at 1722–24, 1728. Dr. Sze testimony at trial demonstrated that A.H.'s MRI scans showed that "she suffered from an [sic] hypoxic-ischemic injury during her gestational life weeks before her birth." Tr. at 1745. He opined

to a reasonable degree of medical probability, consistent with Dr. Shimony, that the injury occurred "probably most likely, prior to 32 weeks of gestational age." Tr. at 1746.

Given the overwhelming evidence presented at trial, the Court's finding on proximate causation with regard to CNM Crowder and the United States is clearly erroneous. In light of the extensive expert testimony that no hypoxic-ischemic event occurred during the labor or delivery of A.H., and given that the record is completely devoid of any expert testimony that such an event occurred during the period from 12:20 p.m. to 2:19 p.m., there is no basis for the Court to conclude that any alleged negligence by CNM Crowder proximately caused an injury to A.H.

D. The use of inferences to support a finding of proximate cause cannot be used in this case because the expert testimony is not sufficient to support such a finding under West Virginia law.

Since Plaintiffs failed to elicit testimony from the experts who testified at trial to establish that CNM Crowder proximately caused an injury to A.H., they now argue that proximate cause can be inferred based on the record in this case. In *Dellinger v. Pediatrix Medical Group, P.C.*, 750 S.E.2d 668 (W. Va. 2013), the West Virginia Supreme Court of Appeals held that a party cannot build a proximate cause finding by stacking one inference upon another because it would be pure speculation. *Id.* at 675–77. Rather, there must be specific expert testimony that causally connects the allegation of negligence to the alleged injury. *Id.* at 677. This is a complex medical case which required expert testimony to prove proximate causation. *See Fitzgerald*, 679 F.2d at 350; *Farley v. Shook*, 629 S.E.2d 739, 745 (W. Va. 2006); *Hicks v. Chevy*, 358 S.E.2d 303, 305 (W. Va. 1987). Without the requisite expert testimony, the use of inferences to prove causation fails to meet the burden of proof on proximate causation: "While petitioner urges that the jury may nonetheless infer proximate cause notwithstanding her lack of medical testimony on this issue, we find there is quite simply nothing upon which a jury may make such an inference beyond abject speculation. The lack of expert medical testimony as to causation was therefore equally fatal to petitioner's case as her failure to present a

disputed issue of material fact on medical negligence." *Dellinger*, 750 S.E.2d at 677 (footnote omitted). Even when the direct causation question is not asked, proximate cause cannot be inferred without expert testimony "of sufficient character" to permit such an inference. *Id.* at 677 n.15.

The expert testimony presented by Plaintiffs in this case clearly does not meet the "sufficient character" standard described in *Dellinger* because none of Plaintiffs' experts established that any injury to A.H. occurred during the period from 12:20 p.m. to 2:19 p.m. Since it is not possible to determine what occurred during that two-hour period, it is pure speculation to try to link that period of time to the outcome of A.H. As *Dellinger* made clear, such speculation cannot be used to prove proximate causation. Moreover, an inference built upon another inference is speculation and cannot be a basis to support a finding of proximate cause. Since there was no testimony that hypoxia occurred during the period from 12:20 p.m. to 2:19 p.m., any inference that CNM Crowder's alleged negligence during that period proximately caused an injury to A.H. would be not reasonable or rational and cannot be supported. *Id.* at 675-77. *See also Huskey,* 29 F.Supp.3d at 729 (inferences cannot be used to prove causation when based on unreliable and speculative expert testimony).

IV. IT WAS CLEAR ERROR TO FIND THAT THE INFANT'S APGAR SCORES WERE ABNORMAL

Apgar scoring is not a within a layperson's knowledge and require the skills and the exercise of clinical judgment of a labor and delivery medical professional to be properly calculated. The purpose of Apgar scoring is to initially evaluate a newborn's functions within the first few minutes of life; it is not something that can be assessed outside the delivery room.[4] Indeed, expert testimony regarding Apgar scoring was elicited from several experts throughout the duration of trial. A.H.'s Ap[gar scores were calculated to be seven at one minute after birth and eight at five minutes after

[4] To be sure, Plaintiffs' nursing expert, Patricia Connors, testified that she was not "aware of any scientific study or publication in the medical literature that says you can predict or you can assign an accurate Apgar score two hours or four hours after birth," nor had she ever seen that done in her fifty years of labor and delivery nursing. Tr. at 398, 437, 442–43. This highlights the inappropriateness of assigning a new Apgar score twelve years after birth.

birth by the RGH labor and delivery staff. No expert witness testified that A.H.'s Apgar score was less than seven at five minutes of birth which is considered a normal score. Tr. at 340, 416, 417, 436, 442, 1003, 1005, 1551-52, 1840-41, 1919.

All the evidence introduced at trial indicated that A.H. had normal Apgar scores, which supports the conclusion that she did not suffer from a hypoxic-ischemic event during labor and delivery. *See Walker v. United States*, 600 F. Supp. 195, 199 (D.D.C. 1985) ("His Apgar scores of seven and eight were indicative of a normal, healthy child . . . ."). As Dr. Graham explained, Apgar scores are recorded by medical personnel who personally observe the infant immediately after delivery, and it is not appropriate for another expert—or layperson for that matter—to reassign those scores. Tr. at 1093. Moreover, John Fassett, who was the only expert critical of CNM Crowder's conduct in this case, admitted that the Apgar scores were perfectly normal. Tr. at 357.

Dr. Landon also testified that "the Apgar scores were seven at one minute and eight at five minutes after birth," and that page 210 of the 2014 task force report provided that "[a] Category I or Category II fetal heart rate tracing, when associated with Apgar scores of seven or higher at five minutes . . . is not consistent with an acute hypoxic-ischemic event." Tr. at 1919. Thus, Dr. Landon opined to a reasonable degree of medical probability that the Apgar scores and the fetal monitoring strip (never being worse than a Category II) indicated that the labor and delivery of A.H. was not consistent with an acute hypoxic-ischemic event. Tr. at 1920. Dr. Bedrick similarly testified that A.H.'s Apgar scores at one and five minutes were "perfectly normal" and did not indicate any hypoxic injury to the brain either during labor and delivery or shortly thereafter. Tr. at 1840–41. *See also Walker*, 600 F. Supp. at 198 ("[T]he most convincing evidence of record that fetal distress was never present, according to [defendant's obstetrics expert], is [the infant's] elevated Apgar scores at birth [of seven and eight] . . . .").

Dr. Peter Giannone stated that A.H.'s Apgar scores at one and five minutes "are very reassuring. You would have to have an Apgar score of five or less at five minutes of life to be consistent with possible neonatal encephalopathy." Tr. at 1551–52. This opinion was further bolstered by Dr. Trock's testimony: "The point is that one has to have Apgar scores [of] five or less at five and ten minutes to have a newborn brain injury. This child's Apgars were seven and eight, so [she] always had normal Apgar scores. So . . . there was no time that this child sustained a brain injury from lack of oxygen." Tr. at 1003, 1005.

Dr. O'Meara, Plaintiffs' causation expert, agreed that the 2014 Task Force Report of the American College of Obstetrics and Gynecology and the American Academy of Pediatrics stated the following: "[I]f the Apgar score at five minutes is greater than or equal to seven, it is ***unlikely*** that peripartum hypoxia-ischemia played a major role in causing neonatal encephalopathy." Tr. at 624 (emphasis added). As other experts testified, this generally accepted conclusion in the 2014 Task Force Report further supports the conclusion that A.H.'s brain abnormalities were not caused by hypoxia at or around the time birth. Tr. at 952–53, 1919-20.

The Court's conclusion that the Apgar scores recorded by hospital staff for the infant were unreliable and should have been lower was not supported by the expert testimony at trial. While the Court stated that its conclusion was based on the testimony by Plaintiffs and the infant's grandmother, no expert considering that same testimony testified that the Apgar score at five minutes after birth was less than seven even after considering that testimony. In fact, Plaintiffs' own experts, CNM Fassett and Nurse Connors, and defense experts Dr. Graham and Dr. Landon, testified that their opinions regarding the Apgar scores were reached after reading the deposition testimony of Plaintiffs and A.H.'s grandmother which mirrored their testimony at trial. Tr. at 340 (Fassett Test.); Tr. at 1094 (Graham Test.); Tr. at 1900 (Landon Test.). Even Nurse Connors, Plaintiffs' nursing expert, agreed that after reviewing photographs and considering the testimony of the family regarding the

appearance of the child after birth, A.H. had an Apgar score of at least seven at five minutes after birth. Tr. at 416-17, 436, 442.

It was inappropriate for the Court to step beyond its role as a lay fact finder to recalculate Apgar scores that are necessarily based on the personal observations and clinical judgment of trained medical personnel moments after a child's birth. The Court's conclusion that its own recalculation of the Apgar scores twelve years after A.H.'s birth was evidence of a perinatal hypoxic injury is contrary to the testimony of all experts in the case as well as the medical literature introduced at trial. The Court's reliance on this ultimate finding is against the manifest evidence presented at trial and clearly erroneous.

V. CONCLUSION

Based on the foregoing, Plaintiffs failed to demonstrate that CNM Crowder's conduct fell below the standard of care, and the Court's finding on that point is clear error. Further, Plaintiffs had ample opportunity to establish that any alleged negligence by CNM Crowder proximately caused an injury to them at trial, but they never elicited any such testimony from any of the numerous expert witnesses who testified during this trial. Plaintiffs now argue that proximate cause can be inferred, but they failed to produce the requisite expert testimony required by *Dellinger* and other cases to allow such inference. Quite simply, based on the whole record, the Court's findings that CNM Crowder breached the standard of care and proximately caused an injury to A.H. were a mistake, not supported by substantial evidence, and clearly erroneous. Plaintiffs have failed to meet their burden of proof under W.Va. Code § 55-7B-3. Allowing judgment in favor of the Plaintiffs to stand against the United States would be a manifest injustice. Therefore, the judgment entered against the United States should be vacated, and judgment should be entered in favor of the United States. *Butts*, 930 F.3d at 241.

Respectfully submitted,

WILLIAM S. THOMPSON
United States Attorney

/s/ Fred B. Westfall, Jr.
Fred B. Westfall, Jr. (WV Bar No. 3992)
Jason S. Bailey (WV Bar No. 13582)
Assistant United States Attorneys
300 Virginia Street, East, Suite 4000
Charleston, WV 25326
Phone: 304-345-2200
Fax: 304-347-5443
E-mail: fred.westfall@usdoj.gov
E-mail: Jason.bailey2@usdoj.gov
Counsel for United States of America

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT BECKLEY

RYAN HYSELL and CRYSTAL HYSELL,
on behalf of their daughter, A.H., a minor,

Plaintiffs,

v. Civil Action No. 5:18-cv-01375

RALEIGH GENERAL HOSPITAL,
and THE UNITED STATES OF AMERICA,

Defendants.

CERTIFICATE OF SERVICE

I, Fred B. Westfall, Jr., Assistant United States Attorney for the Southern District of West Virginia, hereby certify that on June 20, 2022, I electronically filed the foregoing **REPLY IN SUPPORT OF DEFENDANT UNITED STATES OF AMERICA'S MOTION TO VACATE, ALTER, AND/OR AMEND THE JUDGMENT ENTERED IN THIS CIVIL ACTION AND/OR FOR NEW TRIAL** with the Clerk of the Court using the CM/ECF system which will send notification to the following CM/ECF participants:

Christopher T. Nace
Matthew A. Nace
Paulson & Nace, PLLC
1025 Thomas Jefferson Street NW
Suite 810
Washington, D.C. 20007
Counsel for Plaintiffs

D.C. Offutt, Jr.
Jody O. Simmons
Offutt Nord PLLC
949 Third Avenue, Suite 300
P. O. Box 2868
Huntington, WV 25728-2868
Counsel for defendant Raleigh General Hospital

C.J. Gideon, Jr.
Bryan Essary
Gideon, Essary, Tardio & Carter, PLC
315 Deaderick Street
Suite 1100
Nashville, TN 37238
Pro Hac Vice Counsel for Defendant Raleigh General Hospital

s/ Fred B. Westfall, Jr.
Fred B. Westfall, Jr. (WV Bar No. 3992)
Assistant United States Attorney
P.O. Box 1713
Charleston, WV 25326
Phone: 304-345-2200
Fax: 304-347-5443
E-mail: fred.westfall@usdoj.gov
Counsel for Defendant United States of America